DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date JAN 21 1997

From Deputy Director, Clinical and Review Policy,
Office of Device Evaluation (HFZ-440)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Personal Health & Hygiene, Inc.
Dr. Brown's Home Drug Testing System

To The Director, CDRH
ORA_____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Kimber C. Richter

Kimber C. Richter, M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved_____ Disapproved_____ Date _____

Prepared by Arleen Pinkos, CDRH, HFZ-440, 1-14-97, 594-1243

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[DOCKET NO. _____]

Personal Health & Hygiene, Inc.; PREMARKET APPROVAL OF Dr. Brown's Home Drug Testing System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Personal Health & Hygiene, Inc., Silver Spring, MD, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Dr. Brown's Home Drug Testing System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of January 21, 1997, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Steven I. Gutman,

Center for Devices and Radiological Health (HFZ-440),

Food and Drug Administration,

2098 Gaither Rd.,

Rockville, MD 20850,

301-594-1243.

SUPPLEMENTARY INFORMATION: On December 19, 1995, Personal Health & Hygiene, Inc., Silver Spring, MD 20910, submitted to CDRH an application for premarket approval of Dr. Brown's Home Drug Testing System. Dr. Brown's Home Drug Testing System is an over-the-counter collection and transport system intended for use by individuals wishing to anonymously test urine samples for drugs of abuse (marijuana, cocaine, amphetamine, methamphetamine, phyencyclidine (PCP), codeine, and morphine).

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Clinical Chemistry and Toxicology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On January 21, 1997, CDRH approved the application by a letter to the applicant from the Deputy Director, Clinical and Review Policy, of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of

this document.

Opportunity For Administrative Review

Section 515(d)(3) of the act,(21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the

heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated:_____.

_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

J. Theodore Brown, Jr., Ph.D.
President
Personal Health & Hygiene, Inc.
8000 Eastern Drive, Suite 201
Silver Spring, Maryland 20910

JAN 21 1997

Re: P950040
Dr. Brown's Home Drug Testing Kit
Filed: December 19, 1995
Amended: January 16, March 15, August 21, October 2, November 14, 27, December 4, 20, and 27, 1996; January 3, 17, and 21, 1997

Dear Dr. Brown:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Dr. Brown's Home Drug Testing System. Dr. Brown's Home Drug Testing System is an over-the-counter collection and transport system intended for use by individuals wishing to anonymously test urine samples for drugs of abuse (marijuana, cocaine, amphetamine, methamphetamine, phyencyclidine (PCP), codeine, and morphine). We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

In addition to the postapproval requirements in the enclosure, a PMA Supplement must be filed anytime significant modifications are made to your device. Some examples include but are not limited to:

1. Changes in the laboratory being used;

2. Changes in laboratory certification;

3. Changes in Result Center Management Group;

4. Changes in services provided by the laboratory or Results Center; and

5. Changes in laboratory procedures, i.e., cut-offs, reagent systems, instrumentation.

Additionally, a Good Manufacturer's Practice (GMP) inspection of your product assembly facility and Results Center location will occur approximately 8 months after your device is operational. Training records and follow-up surveillance of telephone representatives, as described in the submission, should be documented and maintained for a period of three years.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Dr. Steven Gutman at (301) 594-3084.

Sincerely yours,

Kimber C. Richter

Kimber C. Richter, M.D.
Deputy Director, Clinical and
Review Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

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(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, 340
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Summary of Safety and Effectiveness Data

I. General Information

Device Generic Name:	Specimen Collection Kit for Drug Abuse Testing
Device Trade Name	Dr. Brown's Home Drug Testing System
Applicant s Name and Address:	Personal Health & Hygiene, Inc. 8000 Eastern Drive, Apt. 201 Silver Spring, Maryland 20910

Premarket Approval Application (PMA) Number: P950040

Date of Panel Recommendation: Pursuant to section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not the subject of an Food and Drug Administration (FDA) Clinical Chemistry and Toxicology Advisory Panel meeting because the information in the PMA substantially duplicates information previously reviewed by this panel.

Date of Notice to Applicant: January 21, 1997

II. Indications for Use

Dr. Brown's Home Drug Testing System is an over-the-counter collection and transport system intended for use by individuals wishing to anonymously test urine samples for drugs of abuse (marijuana, cocaine, amphetamine, methamphetamine, phencyclidine (PCP), codeine, and morphine).

For in vitro diagnostic use only.

Background

Dr. Brown's Home Drug Testing System (hereinafter referred to as the System) is a specimen collection system for drugs of abuse testing, sold over-the-counter (OTC). The consumer submits a urine specimen for analysis to a laboratory which is certified to perform drugs of abuse testing. The laboratory tests human urine specimens that are mailed from various locations in the United States for seven drugs of abuse; marijuana, cocaine, amphetamine, methamphetamine, PCP, codeine, and morphine. The laboratory screens the urine specimens with legally marketed devices. All positive test results are confirmed with gas chromatography/mass spectroscopy (GC/MS) prior to results being reported to consumers. Consumers obtain results over the phone using an anonymous identification number.

Some examples of similar systems currently in use include:

In Cobb County, Georgia, a form of home based drug testing has been utilized. Parents were provided with urine specimen containers for the purpose of obtaining a urine sample from their child. They submitted the specimen to a hospital emergency room for analysis, then called a physician several days later to obtain the results. It was reported that the program resulted in a reduction of substance abuse among adolescents in that community.[1]

Kilgore, Texas has a youth sponsored drug prevention program which emphasizes random drugs of abuse testing. Individuals are randomly selected to submit a specimen at the local police station for analysis. Youth who participate in the program are given a membership card to identify themselves, and are eligible for certain privileges (i.e. discounts on clothes, sports participation, etc.). The program has been reported to be successful in reducing the incidence of drug abuse among adolescents in the Kilgore Community.[2]

Pretrial Services in the District of Columbia has been using random drug testing as a deterrent and means of early detection of substance abuse. Pretrial Services was able to claim a success rate for deterring its clients from using drugs.[3]

Contraindications

There are no known contraindications for Dr Brown's Home Drug Testing System.

Warnings and Precautions

This device is not appropriate for testing that is to be used as evidence in the legal system.

Additional Warnings and Precautions for use of the device are stated in the attached product labeling (See Attachment A.)

III. Device Description

The System package consists of two plastic urine collection/storage containers, a pre-addressed, postage paid mailing container, instructions for use, and a unique identification label which is affixed to both the sample tubes and the instructions. The System provides laboratory testing, and phone access to counselors who provide referrals to counseling and medical services. To use the System, the lay user first purchases the device then collects a

urine sample in the containers provided. The user must retain the identification number on the instructions as it is required to obtain the test results. The user places the containers in the pre-paid mailer and sends them to the laboratory via the U.S. Postal Service.

The specimen is received at the designated laboratory where proper labeling and the date of collection are noted. The sample is logged into a computer system according to the unique identification number, evaluated for possible tampering, i.e., liquid added to the sample; then analyzed to determine if significant levels of drugs of abuse (marijuana, cocaine, amphetamines, methamphetamine, PCP, codeine, and morphine) are present. Results and important information pertaining to labeling, age of the specimen, or suspected adulteration are entered into the laboratory computer system. When the consumer calls for the results, Personal Health & Hygiene (PH&H) representatives access the laboratory information using the anonymous identification number. If the specimen was delayed beyond 7 days in the mail or was lost, PH&H will offer the user an additional device at no cost.

The designated laboratory is certified by two recognized laboratory certifying bodies; the College of American Pathologists (CAP) and Substance Abuse and Mental Health Services Administration (SAMHSA). The laboratory performs integrity checks on each sample (creatinine, specific gravity, observations for unusual odor or appearance) in order to detect possible tampering. Two types of analyses are performed; the first is a screening test run on an automated analyzer. All positive results obtained in the screening process are then confirmed by a second type of analysis, gas chromatography/mass spectroscopy (GC/MS), a sensitive and specific methodology. GC/MS is widely recognized as the reference method for identifying drugs of abuse.

Within one to three days after the specimen has been received in the laboratory, test results are available. The consumer phones a toll free number for the PH&H Results Center, Monday through Saturday, during designated hours. After consumers identify themselves by the unique identification number, test results are provided; either that marijuana, cocaine, amphetamine, methamphetamine, phencyclidine (PCP), codeine, and/or morphine is or is not present in the urine. Information pertaining to the meaning of the results, limitations of the test, and the possibility of false negative or positive results is given to the consumer. In addition, names and telephone numbers of facilities that can provide medical assistance and substance abuse counseling services are made available. Selections, which are based on the caller's zipcode, are made from two nationally recognized lists of substance abuse counseling and medical services: The National Directory of Drug Abuse and Alcoholism Treatment and Prevention Programs; and the American Society of Addiction Medicine Directory.

IV. Alternative Practices and Procedures

Testing in a medical setting consists of obtaining a physician's request for testing the urine, and then performing the analyses at a clinical laboratory. Results are then forwarded to the physician, who relays the findings to the individual

Other alternative practices for drugs of abuse testing involve the analysis of other matrices, i.e., blood or sweat. These testing procedures are currently not available over-the-counter, but may be obtained through a health care professional.

V. Marketing History

Dr. Brown's Home Drug Testing System was initially marketed in the United States because the applicant thought that FDA review was not required. When the applicant discovered that FDA approval was needed to legally market the device, marketing of the system halted and a PMA was submitted

VI. Potential Adverse Effects of the Device on Health

Adverse effects of drugs of abuse testing include the damage that might occur if an individual were misclassified due to a false positive or false negative result. A false positive result erroneously identifies a person as using illegal drugs and could, therefore, impugn their reputation. A false negative result fails to identify a person as using illegal drugs and would therefore cause the individual requesting the testing to miss the opportunity to obtain treatment for the problem.

There is also a potential for inaccurate results if an individual tampers with the sample. If liquids or other interfering substances are added to the urine, drugs present in the sample may not be detected

VII. Summary of Studies

A. Non-Clinical Studies

The FDA, as a scientific agency, has addressed a number of concerns while evaluating the safety and efficacy of this device:

1. Stability of Drugs of Abuse in Urine Samples

Stability requirements necessary for this type of device have been established by several independent sources which are available to the public; there have been stability studies documented in the literature which support the fact that various drugs contained in urine samples remain stable for 7 days under conditions

equivalent to those expected during shipment through the U.S. Postal Service [4,5]; a 1991 PMA FDA Advisory Panel Meeting determined that drugs of abuse were sufficiently stable in urine to accommodate the intended use of these types of products [6]

2. The mailer complies with U.S. Postal Regulations for transport of biological materials

3. The urine collection tube is adequate for collection and storage of urine samples to be analyzed for drugs of abuse. The tubes are made of polystyrene plastic and have screw-on tops which, when tightened appropriately, prevent leakage. These tubes are routinely used in the laboratory to store biological specimens because they do not leach chemicals into or absorb drugs out of the urine. These tubes, when used by professionals, are a Class I, exempt device. They have, however, been cleared by the 510(k) process for use by professionals to store urine samples to be analyzed for drugs of abuse under chain-of-custody.

4. The testing laboratory is credentialed by several drug testing authorities.

   The designated laboratory is certified by two recognized laboratory certifying bodies; the College of American Pathologists (CAP) and Substance Abuse and Mental Health Services Administration (SAMHSA). In addition, the laboratory is licensed by the Health Care Financing Administration under the Clinical Laboratory Improvements Act (CLIA)

5. Laboratory results are accurate and reliable

   Specimens are evaluated for integrity and standard industry protocols for monitoring quality control and quality assurance of the system are in place; only legally marketed assays are used to screen the sample for drugs; and a reference method acceptable to SAMHSA is used to confirm positive samples. A computerized system is in place to transmit laboratory results to PH&H telephone representative in a timely fashion

   The laboratory uses products for screening the samples that are legally marketed. The cut-off levels used in the screening tests are: cannabinoid metabolites, 20 ng/mL; cocaine metabolites, 300 ng/mL; morphine and codeine, 300 ng/mL; PCP, 25 ng/mL; and amphetamine and methamphetamine metabolites, 1000 ng/mL.

   The laboratory follows SAMHSA workplace drug testing accreditation program guidelines during the confirmation process, although SAMHSA does not sanction

the use of this product. Guidelines recommend that specimens identified as positive by the screening test be confirmed using a GC/MS technique, and should be considered positive at the following cut-off levels; cannabinoid metabolites, 15 ng/mL; cocaine metabolites, 150 ng/mL; morphine, and codeine, 2000 ng/mL; PCP, 25 ng/mL; and amphetamine and methamphetamine metabolite, 500 ng/mL.

6. An evaluation of the labeling for reading comprehension was conducted and demonstrated that information given to the consumer was understood and interpreted correctly.

During this study, 30 individuals were randomly selected at a Washington D.C. location to read the package insert, then answer questions which evaluated their understanding of the labeling. The survey consisted of 16 questions.

Survey Results: A total of 70 percent of the participants responded correctly to all 16 questions 20 percent missed 1 question, and 10 percent missed 2 questions.

B. Clinical Studies

1. Pilot Evaluation

a. Description

A pilot evaluation of the System was conducted over a 6 month period, beginning in 1990. The purpose of the evaluation was to demonstrate that: 1) the System was effective in detecting marijuana, cocaine, amphetamines, PCP, and opiates in urine samples submitted by lay persons; 2) the directions for use were adequate; and 3) that participants understood the information provided in the labeling. The product used in the evaluation was an earlier version of the device, differing in several ways from the final device which will be commercially available: the size of the urine collection tube was smaller, labeling was more abbreviated, and different laboratory screening assays were used. In addition, analyses performed during this pilot did not include GC/MS confirmation testing. Confirmation testing is the only way that types of amphetamine and opiates can be discriminated from each other.

During the pilot evaluation, individuals purchased the System through mail order or during public speaking engagements where the product was being promoted in the Washington D.C. area. When individuals who had sent a sample to the laboratory called in for the results they identified themselves by the unique identification number. Survey questions were randomly posed to a subset of the callers for the purpose of evaluating overall impressions and satisfaction with the product, and to obtain demographic information on the participants.

b. Pilot Evaluation Results

1) Ninety-five per cent of individuals who purchased the device were able to successfully mail a sample to the laboratory and obtain the test results over the phone. The applicant was unable to provide an explanation for why some of the System purchasers failed to send a specimen to the laboratory. Phone survey participants generally expressed approval for the product:

- Ninety-nine percent said they would use the device again.
- Ninety-nine percent stated they had no problems understanding the labeling.
- Ninety-nine percent indicated they did not need professional assistance to use the device.
- Eighty-one percent stated that the device reduced the inclination to use drugs.
- All participants responded that their reason for using the device was to either: help a person in recovery, prevent drug use, or because they suspected drug use.

2) During the pilot evaluation, 251 demographically diverse individuals, between the ages of 19 and 53, with an average age of 36 years, income of $43,000, and education of 14.7 years, purchased the System. A total of 238 of the 251 individuals who purchased the device mailed samples to a CLIA certified laboratory where analysis was performed. The average age of individuals providing the samples was 10.5 years. Survey questions were randomly posed to 229 of the 238 individuals who had sent a sample to the laboratory and were calling in for the results.

3) Of the 238 samples analyzed, the following percentages of positive results were obtained, marijuana, 16 percent; cocaine, 8.5 percent; amphetamines, 3 percent; opiates, 3.5 percent; and PCP, 6 percent.

2. Follow-Up Evaluation

a. Description

At FDA's request, in an attempt to follow up on the accuracy of Pilot Evaluation conclusions, approximately 300 individuals who were believed to have used the product during or after the Pilot Evaluation, were contacted by community and church leaders who worked with the applicant during the pilot program. Networking with community leaders was the only way to reach these individuals as the original study was conducted anonymously. Information was collected from

November 1995 to June 1996. Individuals were asked to answer 13 multiple choice questions for the purpose of evaluating the effect the device had on all individuals involved with the System, and also to reaffirm their impressions of the System. Of those contacted, 166 identified themselves as having used the System and agreed to respond to the Follow-up Survey Questionnaire.

FDA recognizes the weakness in any conclusions drawn from this study, due to the anonymity of pilot and follow-up participants.

b. Follow-Up Study Results

Survey results indicated that participants believed the device was beneficial as an aid to deterring drug use and that risks associated with using the System were low.

VIII. Conclusions Drawn from the Studies

Conclusions and Information Presented

A. Urine samples collected by lay users were tested by a qualified laboratory and were identified as containing significant levels of marijuana, cocaine, amphetamines, PCP, and/or opiates.

B. Published data adequately supported the fact that drugs in urine specimens remain sufficiently stable unpreserved for up to 7 days, allowing shipment by mail to the testing laboratory.

C. The urine collection tubes were adequate for storing urine samples to be analyzed for drugs of abuse.

D. The mailer was safe for transport of biological materials through the U.S. Postal Service.

E. The labeling adequately conveyed the meaning of test results and limitations of the testing procedures to lay users.

F. The System was viewed as having minimal risk.

G. The System provided access to a national network of health care providers specializing in substance abuse counseling and related health care services.

IX. Panel Recommendations

The FDA does not believe that a panel meeting is necessary to evaluate the safety or effectiveness of this device since a similar product was recommended for approval by the Clinical Chemistry and Toxicology Devices Panel on November 4, 1991. Under SMDA 1990, §515 (c)(2), a PMA need not be referred to the Advisory Panel if their review will substantially duplicate issues that the Panel has considered before.

X. FDA CDRH Action on the Application

CDRH issued an approval order for the applicant's PMA for Doctor Brown's Home Drug Testing System on January 21, 1997.

The Results Center will be inspected approximately 8 months after marketing begins for compliance with the Good Manufacturing Practice Regulations (GMPs). An adequate evaluation of this facility cannot be conducted before the System is operational.

There is no shelf-life for Doctor Brown's Home Drug Testing System. Expiration dating for products used in the laboratory are determined during the FDA 510(k) process.

XI. Approval Specifications

Directions for Use: See Labeling (Attachment A)

Conditions of Approval: CDRH approval of the application is subject to compliance with the conditions described in the approval order (Attachment B)

BIBLIOGRAPHY

1 Adolescent Urine Drug Screening
A Cobb County Medical Society Program
Journal of the Medical Association of Georgia
p 833-837, December 1987

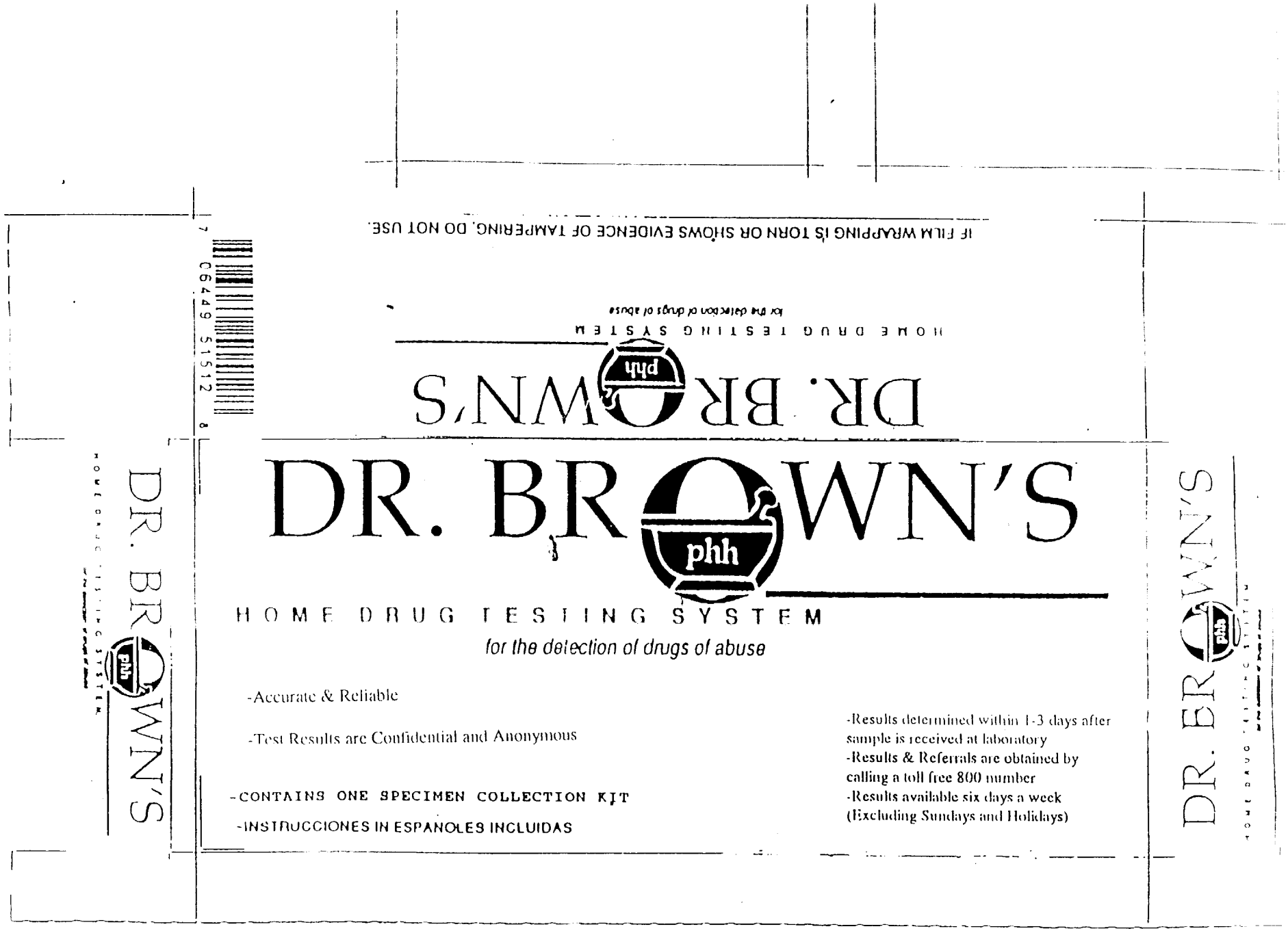
2 Kilgore Youth Stand Superior Eliminating Drugs, KYSSED Program
Letter & Brochure to Dr. Brown
November 14, 1995

3 Day Programs Sought for Drug Addicts
Loeb, Vernon
Washington Post, March 6, 1996, P.8

4 Fringe R.S. and Queen C.A.
Direct Solvent Extraction Method for Detecting Drugs of Abuse in Urine: Comparison with Resin Column Methods
Clinical Chemistry 18, 563 (1972). Abstract.

5 Effect of Specimen Storage and Preservation on Toxicological Analyses of Urine
Rockerbie RA and Campbell DJ
Clinical Biochemistry 1978; 11:77-81

6 AWARE Test System PMA Submission; Summary of Safety and Effectiveness Data;
December 13, 1990. Pages 3-4


IF FILM WRAPPING IS TORN OR SHOWS EVIDENCE OF TAMPERING, DO NOT USE.
HOME DRUG TESTING SYSTEM
for the detection of drugs of abuse
DR. BROWN'S
phh
DR. BROWN'S
HOME DRUG TESTING SYSTEM
for the detection of drugs of abuse
-Accurate & Reliable
-Test Results are Confidential and Anonymous
-CONTAINS ONE SPECIMEN COLLECTION KIT
-INSTRUCCIONES IN ESPANOLES INCLUIDAS
-Results determined within 1-3 days after sample is received at laboratory
-Results & Referrals are obtained by calling a toll free 800 number
-Results available six days a week (Excluding Sundays and Holidays)
DR. BROWN'S
HOME DRUG TESTING SYSTEM
C6449 51512 8

DR. BROWN'S

HOME DRUG TESTING SYSTEM

for the detection of drugs of abuse

ACCURATE - RESULTS IN 3 DAYS - EASY TO USE - CONFIDENTIAL AND ANONYMOUS

The Only Way to Obtain Test Results is with the Identification Number

Manufactured by Personal Health & Hygiene, Inc.
5125 MacArthur Blvd., Washington, D.C. 20016

INTENDED USE

DR. BROWN'S HOME DRUG TESTING SYSTEM is an over-the-counter collection and transport system intended for use by individuals wishing to anonymously test urine samples for drugs of abuse (marijuana, cocaine, amphetamine, methamphetamine, phencyclidine(PCP), codeine and morphine).

THIS TEST MAY NOT BE USED FOR LEGAL PURPOSES. THIS TEST IS FOR USE OUTSIDE OF THE BODY

CONTENTS:

The device consists of two plastic urine collection tubes, a foam block container, absorbent pad, absorbent pouch, instructions, identification number and pre-printed mailing pouch. PAT # 4,949,040

BENEFITS OF THE HOME DRUG TESTING SYSTEM:

(1) Accurate and Reliable Results (2) Test Results are Confidential and Anonymous (3) Easy to Use Four Easy Steps in Four Easy Steps

GUARANTEE:

DR. BROWN'S HOME DRUG TESTING SYSTEM guarantees that all test results are completely anonymous. No names are ever associated with test results. If your kit is defective in any way, PH&H will refund the purchase price or replace your kit. A valid identification number is required for any refund or replacement. You must read and follow all kit instructions. PH&H is not responsible for any failure to follow kit instructions.

DO NOT THROW AWAY THESE INSTRUCTIONS.
THIS IS THE PERSONAL IDENTIFICATION NUMBER.
SAVE THIS NUMBER TO RECEIVE The TEST RESULTS!

CONSUMER'S IDENTIFICATION NUMBER

INSTRUCTIONS FOR USE

Dr. Brown's Home Drug Testing System (THE "SYSTEM") for Home Collection of a Urine Sample to Detect Substances of Abuse

IMPORTANT

Read entire instruction insert before use.

Table of Contents

Save The Identification Number

The System Identification Number appears at the top right corner of this page. Check to make sure that this number is the same as the numbers on the Urine Collection Tubes. **Take care of this Identification Number. If you lose it, you will not be able to get the test results! Keep this instruction book in a safe place!**

If you need help while using the System, call 1-800-XXX-XXXX for assistance.

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WARNINGS

1. There is a possibility that other substances and/or factors may interfere with the test and cause false results. (e.g., technical or procedural errors.

2. Urine specimens may be infectious. Wash hands thoroughly prior to, and after, handling urine specimens.

3. Some medicines and foods such as cough medications, inhalers, anti-diarrhea medicines, and poppy seeds, may cause positive test results.

4. If you believe that something has been added or done to the urine sample, do not send it in. Obtain another sample of urine for testing.

5. If you do not follow the directions as indicated, the test results may be incorrect, or the sample may not be tested.

6. Fill both urine collection tubes to the top or the sample will not be tested.

7. After collecting a urine sample, mail it right away.

8. In order for the results to be accurate, the laboratory must receive the urine sample within seven (7) days after it is collected. Samples received more than seven (7) days after collection will not be tested.

9. Being in a room repeatedly with extremely heavy marijuana smoke (smoke exhaled by others in a confined space) may result in a positive test for marijuana.

10. In some cases the legal rights of the donor may be violated if the urine sample is collected or tested without their consent.

LIMITATIONS OF DR. BROWN'S HOME DRUG TESTING SYSTEM

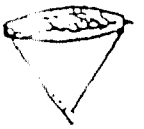
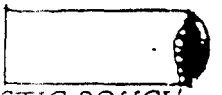
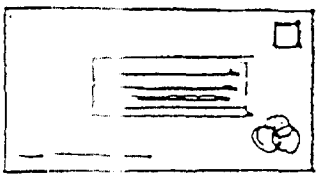
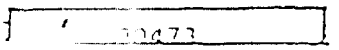
1. This test is for use outside of the body.

2. This test is not valid for legal purposes.

3. It should only be used to collect urine samples to detect the drugs of abuse identified in this brochure.

4. Liability of the System is limited to the purchase price of the System.

CHECKING THE SYSTEM
MAKE SURE THE SYSTEM HAS ALL OF THE PARTS LISTED BELOW!

 URINE COLLECTION TUBES	Used to Collect & Store Urine
 PAPER CUP	Makes Pouring Urine Sample into Collection Tubes Easier
 STYROFOAM BLOCK	Helps to Prevent Leaks & Spills, also Protects the Urine Collection Tubes
 PLASTIC POUCH	Protects Against Leaks from Urine Collection Tubes
 ABSORBENT PACKET	Guards Against and Absorbs, Leaks and/or Spills from Urine Collection Tubes
 PREPAID MAILER	Used for Shipping and Protection of Sample. and has a Place for You to Record the Date You Collected the Sample
 IDENTIFICATION NUMBER	Identifies the Urine Sample

IMPORTANT: The Identification Number appears in 2 places. These numbers are the only link between you and the test results. <u>It is very important that these numbers all be the same or you may get someone else's results.</u> Check each item carefully. If all numbers are not the same, call customer service at 1-800-XXX-XXXX.

The Identification Number appears in the following areas:

- **On the front of these instructions.**
- **On each of the <u>two</u> urine sample tubes.**

All of the parts shown above should be in your Dr. Brown's Home Drug Testing System (the "System"). If any of the parts are missing, call our customer service number 1-800-XXX-XXXX to order a new drug testing System. You must have the Identification Number to make the call.

WHAT IS DR. BROWN'S HOME DRUG TESTING SYSTEM?

Dr. Brown's Home Drug Testing System:

1. Is a drug abuse testing service.

2. Is an educational tool.

3. Is a source of referrals to health care network services.

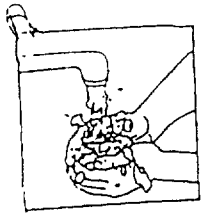
4. Contains all of the parts needed to collect and send a urine sample to the laboratory for testing.

5. Detects marijuana, cocaine, amphetamine, methamphetamine, phencyclidine (PCP) codeine and morphine in urine, without knowing, or telling, the name of the person being tested.

...or best results, read all the directions first. Then follow the step-by-step guide to make sure you collect enough urine to fill both tubes for proper testing.

Step #1 HOW TO COLLECT A URINE SAMPLE

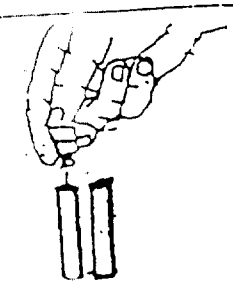
IMPORTANT. Do not throw away plastic bag with white absorbent packet. You will need them again for mailing the sample.

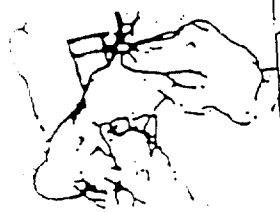


A. Wash hands thoroughly.

Remove the caps from urine collection tubes.

B.

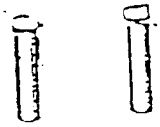




Dry off the outside of the Urine Collection Tubes.

Squeeze the paper cup to make a spout.

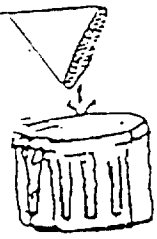
C.



Make sure there is an Identification Number label on both tubes, and that both numb match the identification Number a beginning of these directions.

Urinate directly into paper cup.

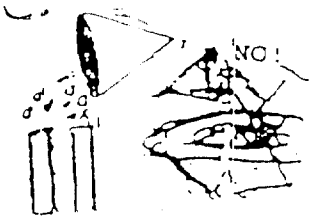
D.

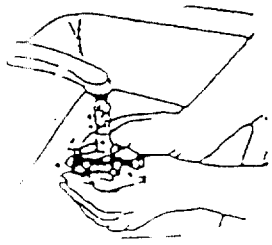


Throw away paper cup.

Pour urine from paper cup directly into both urine collection tubes. You must fill both tubes! Do not take urine from the toilet.

E.





Wash your hands.

Put caps back on urine collection tubes and screw on tightly.

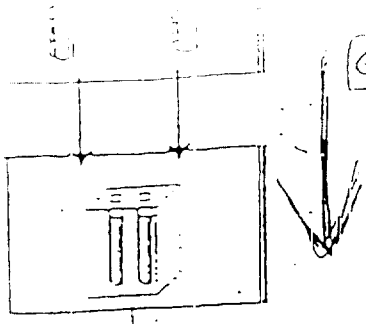
F.

FOR HELP CALL 1-800-XXX-XXXX.

REMEMBER TO CHECK THAT ALL IDENTIFICATION NUMBERS AGREE:

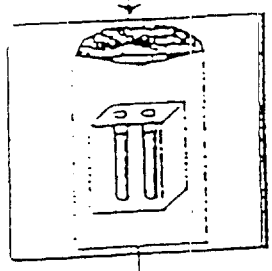
- On the front of these instructions
- On each of the two urine collection tubes

A. Put both Urine Collection Tubes into the Foam Block.



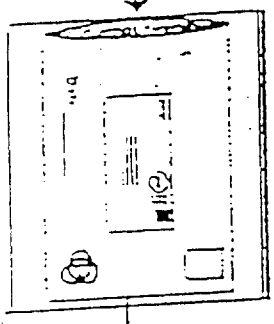
B. Put the Foam Block, with both Urine Collection Tubes, into the Plastic Pouch. The white pad remains in the Plastic Pouch to absorb spills.

Seal the plastic pouch closed.



C. Put the Plastic Pouch (with white pad) into the Prepaid Mailer.

D. Close and seal the Prepaid Mailer.



E. Write date Urine Sample was collected in area marked Date_____on the front of the Prepaid Mailer

F. Put the Prepaid Mailer into any U.S. Postal Mailbox. Mail Right Away!

Urine samples over 7 days old will not be tested.

Results will be ready 1-3 days after the sample arrives at the laboratory

[GRAPHICS MOVE DOWN]

Step #3 GETTING THE RESULTS

A. To get results, you must have the Identification Number. Please have a pencil and paper ready when you call

B. Dial 1-800-XXX-XXXX.

C. Please listen with care and follow all directions

D. You will be given a result for each of the drugs tested; either that the drug was or was not found in the urine. You will also receive an explanation of what the results mean, and phone numbers of drug counselors and doctors that can help you.

AVAILABILITY OF RESULTS

A. Results should be ready within 1-3 business days after the sample arrives at the laboratory. This is usually 2 to 6 days after the sample is mailed. (Excluding Sundays and Holidays)

B. You can call for results Monday through Friday, 8:00 A.M. to 8:00 P.M. (E.S.T.) , and on Saturday from 10:00 A.M. to 6:00 P.M. (E.S.T.) (Excluding Sundays and Holidays)

C. If the sample is delayed beyond seven (7) days or is lost in the mail, you may be able to receive another System at no cost. Call our Customer Service Department at 800-XXX-XXXX with the Identification Number, date of purchase, and your address. A replacement System will be sent to you.

D. **Test data will be kept on file for thirty days after results are received.** You may call any time within that thirty day period to discuss the results. Remember to have the Identification Number in order for us to access the test results. After thirty days, results will be discarded

WHAT THE RESULTS MEAN

1. We test every urine sample for seven (7) drugs
   Marijuana, Cocaine, Amphetamine, Methamphetamine, PCP, Codeine, and Morphine.
   More detailed information about laboratory testing is available by calling 1-800-XXX-XXXX.

2. You will either be told the urine tested positive for a drug or negative for a drug. A positive result means the drug was found in the urine. A negative result means it was not found in the urine.

3. There are two tests done on the urine sample before a positive test result is given. If a drug is detected by the first test, a second, more reliable and accurate test is done as a double check.

4. The two step testing process is accurate and reliable.

5. If the sample tests negative on the first test, a second test is not performed.

6. Some medicines and foods such as cough medications, inhalers, anti-diarrhea medicines, and poppy seeds, may cause positive test results.

7. Once in the body codeine and heroin are broken down to morphine so a positive morphine result may be due to the individual taking morphine, codeine or heroin.

8. Remember that a person does not have to smoke or eat marijuana to test positive for the drug. Being in a room repeatedly with extremely heavy marijuana smoke may cause a positive marijuana test.

9. When a drug is found in the urine:
   - It does not tell how the drug was taken (smoked, injected, swallowed or inhaled).
   - It does not tell if that drug was prescribed by a doctor.
   - And it does not tell if the positive result is due to something the person ate.

10. If no drugs are found in the urine, the person tested has probably not used drugs within the last few days. However, a person can use drugs, but not have drugs found in their urine. Some examples are:

    a. If a person takes (or uses) only a small amount of a drug, it may not show up in the urine test.

b. When a person takes (or uses) a drug, it takes a couple of hours to get into the urine, and then it will only be in the urine for a few days. So, if the urine sample is taken too early or too late, even though the person took drugs, no drugs will be found in the urine.

c. If something is done to the urine, such as adding water, test results may be incorrect.

d. If a person drinks a lot of liquids within a few hours of giving the sample, you may get incorrect test results.

e. The System only tests for 7 drugs. There are many other illegal drugs that may have been used. If a person takes drugs other than those tested for by the System, the test results will be negative.

11. The System is designed to detect some substances of abuse in urine samples taken at home. **You should not say or do anything harmful to anyone based on a test result.** If you are told that drugs were found, our staff will help you identify a medical, substance abuse, or mental health expert to talk to.

12. **Anytime you receive a positive result, or you do not believe a test result, you should consult a doctor.** They can provide more complete information about the meaning of the test results because they are familiar with personal medical history.

Information Provided to Customers by Telephone Representatives

Telephone Representatives are trained to respond to seven (7) basic categories of calls from consumers calling for test results.

1. Request for Referrals
2. Positive Test Results
3. Negative Test Results

Special Conditions

4. Test Results Not Available
5. Specimen Not Tested
6. Technical Questions about Laboratory, Drugs Tested for and Cutoff Levels
7. Emergency Calls

The Telephone Representatives are trained to assume the worst case scenario for each call. They are trained to prepare for calls from emotional parents, suicidal addicts and families of emotionally disturbed patients. All callers will remain anonymous until they confer with the health provider or facility accepting their appointment for evaluation. Telephone Representatives will always encourage callers to see a health care professional as soon as possible for a preliminary medical evaluation as indicated by either a positive or negative test result.

Requests for Referrals

Requests for referral from callers who have purchased the System will be accommodated to provide the most appropriate referral in accordance with their needs. All Telephone Representatives will be able to access a National Database of Medical, Mental Health, Substance Abuse programs within a customer's geographical area to facilitate the referral process. The callers will receive a 1-800 number referral for phone information, counseling and referral services. In addition, as required or requested, they will be referred to the appropriate health organization or provider, according to their zip code number

TEST RESULTS CENTER PROTOCOL

Home Drug Testing Results 800 Number Support Line

Support Line Objectives:

1. Communicate test results to patients who have purchased the home drug test kit.
2. Verify that the caller understands the results and has all questions answered.
3. Refer callers to health care professionals or centers to confirm test results and/or provide treatment for substance abuse issues.
4. Provide customers with a sense of compassion and competence on the part of the Telephone Representatives.

Telephone Representative will communicate any of the following messages as needed based on the caller's questions and will offer the patient referrals to various treatment providers and facilities in their area. The Telephone Representative can also describe different treatment methods that each center might utilize. Callers will be given the name and phone number of the provider and/or organization the Telephone Representative has referred them to, and encouraged to retain their Identification Number and to call back if they experience any difficulties or have questions. This procedure better assures the caller's anonymity and confidentiality. When necessary, the Telephone Representative will utilize active listening skills to help the caller to calm down and work constructively with their feelings of anger or anxiety. In extreme cases, as needed, the Telephone Representative will connect the caller with a local hotline for suicide prevention or contact emergency services.

Telephone Representative's Script

General Opening Script to all Callers:

Thank you for calling Dr Brown's Home Drug Testing System's Result Center. This is (name). How may I help you?

(Caller states need: request for test result.)

May I have your Identification Number please?

(Caller provides Identification Number, and Telephone Representative repeats back.)

I want to make sure that I have the right number. That number was xxx-xxxx. Is that correct?

(Caller confirms the Number)
Allow me a minute to get your results.

We test every urine sample for seven (7) types of drugs: Marijuana, Cocaine, Amphetamine, Methamphetamine, PCP, Codeine, and Morphine.

You will either be told the urine tested positive for a drug or negative for a drug. A positive result means the drug was found in the urine. A negative result means it was not found in the urine.

If any results were positive:

Sir/Madame, my records show that we *did* find drug(s) in the urine sample you sent to us.

Do you want to write the results down? Do you have a paper and pencil to write the results down? (Wait if necessary.)

The drug(s) we found in the urine was(were) [List drugs found].

Let me tell you a little about what these results mean:

The laboratory always does two different tests on the urine specimen; the first test identifies the drug; the second test is more reliable and accurate, and acts as a "double check" on the first test.

You should know that some medicines and foods such as cough medications, inhalers, anti-diarreah medicines, and poppy seeds, may cause positive test results. There are other medications, both over-the counter and prescription, that can cause a positive [name of drug] result.
Note:
Telephone Representatives will have access to the most current DH&HS Workplace Programs document "List of Prescription and Nonprescription Drugs that Could Affect a Drug Test". This list will be referenced if the caller has a specific question about a particular drug.

Remember that being in a room repeatedly with extremely heavy marijuana smoke may cause a positive marijuana test even though that person did not smoke marijuana themselves.

You should also know that when a drug is found in the urine:

- It does not tell how the drug was taken (smoked, injected, swallowed, or inhaled).
- It does not tell if that drug was prescribed by a doctor.
- And it does not tell if the positive test was due to something the person ate.

Any time you receive a positive result or you do not believe a test result, you should consult

with a doctor. They can provide more complete information about the meaning of the test results because they are familiar with personal medical history.

To be read any time the lab reports that creatinine and specific gravity results are out of range:

Sir/Madame, my records show that the urine sample may have been diluted. Diluting a sample can cause a negative result even though the person may have been using drugs. The two most common ways this can happen are:

1. The person added liquid to their urine sample or
2. The person drank a lot of liquids within a few hours of giving the sample.

If some or all tests are negative:

Sir/Madame, my records (also) show that the urine sample you sent us did not have [List drugs] in it.

This means that the person tested probably did not use this(these) drug(s) within the last few days. You should know, however, that it is possible for a person to take drugs, but not have drugs in their urine at the time it was collected. Let me give you a few examples:

- If a person takes only a small amount of a drug, it may not show up in the urine.
- When a person takes a drug, it takes a couple of hours to get into the urine, and then it will only be in the urine for a few days. So, if the urine sample is taken too early or too late, even though the person took drugs, no drugs will be found in the urine.
- It is also possible that the person may have done something to the urine. If this happens you may get incorrect test results.
- The person drank a lot of liquids within a few hours of giving the sample.

There are other drugs that a person could be taking besides the ones we test for. If we do not find any drugs in the urine, the person tested may be using other drugs. You may want to talk to your doctor about testing for other drugs.

General closing script:

If you believe for any reason that these test results are wrong, we suggest that you repeat the test. Although our tests are reliable, no test system is correct 100% of the time.

I am not a drug expert so I cannot give you advice. But I would like to give you the names and phone numbers of some people who can help you and answer your questions about drug abuse. I can offer you either names of counselors who deal with drug use or medical doctors in your area [Provide names and phone numbers.]

If you decide later that you want these phone numbers or if you have any other questions that I can help you with, please call this number again and we will be happy to help you. You will need your Identification Number to do this, so remember to keep it in a safe place.

SPECIAL CONDITIONS

Test Results Not Available

If test results are not available when the consumer calls for results, the Telephone Representative will determine the cause:

1. If the consumer did not follow directions, i.e., they did not mail the sample within 2 days after collection, or the sample was adulterated, they are informed that they need to purchase another System and follow the directions carefully so that the sample can be tested.

2. If the sample could not be tested due to no fault of the consumer, i.e., the sample was lost in the mail, lost by the laboratory, tubes were damaged and/or leaked, or if bar codes are missing or illegible, PH&H will furnish a replacement System at no cost.

The Telephone Representative has access to the following information from the laboratory in order to assist them in making these determinations: date sample was received; if the sample was not received within 7 days after collection; if the sample is suspected of being diluted; if the sample is adulterated; and if there is a sample identification problem.

Technical Questions about Laboratory, Drugs Tested For, and Cut-off Levels

If a caller asks about the quality of the laboratory, the tests, the drugs tested for, or the cut-off levels, the phone representative will indicate that the lab is certified to perform drug tests and the chemicals and tests used are produced by Roche Diagnostic Systems, Inc. The procedure used for the first test is called an immunoassay test, and for the second, is a confirmation test by Gas Chromatography/Mass Spectrometry (GC/MS). The Representative will also quote the cut-off levels used.

Caller: "What type of Laboratory tests the sample?"

Response: "Sir/Madame, the lab that performs the tests is certified to test for drugs of abuse by the Substance Abuse and Mental Health Service Administration (SAMHSA), the College of American Pathologists (CAP) and several states including New York, Florida and Maryland. These organizations certify the laboratory but not the specific "System."

Caller: "Where do the test supplies and chemicals come from?"

Response: "The chemicals and tests used are produced by Roche Diagnostic Systems, Inc. ."

Caller: "What is the name of the test procedure?"

Response: "The procedure used for the first test is called an immunoassay test. If that test shows that drugs are in the sample, a second test called a Gas Chromatography/Mass Spectrometry (GC/MS) is done to confirm that the first test was accurate."

Caller: "What are the cut-off levels used?"

Response: "The cut-off levels used are:

DRUG	SCREENING	CONFIRMATION
Marijuana	20 ng/mL	15 ng/mL
Cocaine	300 ng/mL	150 ng/mL
Amphetamine	1000 ng/mL	500 ng/mL
Methamphetamine	1000 ng/mL	500 ng/mL
Codeine	300 ng/mL	2000 ng/mL
Morphine	300 ng/mL	2000 ng/mL
PCP	25 ng/mL	25 ng/mL"

Caller: "What does a positive test mean?"

Response: "A positive result means that drugs were found in the urine and that the person tested has probably used that drug.

-It does not tell you how they took the drug (smoked, injected, swallowed or inhaled).
-It does not tell you if that drug was prescribed by a doctor.
-And it does not tell you if it is caused by something they ate.

Remember that being in a room repeatedly with heavy extremely heavy marijuana smoke may cause a positive marijuana test even though that person did not smoke marijuana themselves.

Anytime you receive a positive result or you do not believe a test result, you should consult with a doctor. They can provide more complete information about the meaning of the test results because they are familiar with personal medical history."

Caller: "What does a negative test mean?"

Response: "This means that no drugs were found in the urine and that the person tested probably did not use drugs within the last few days.

You should know, however, that it is possible for a person who is taking drugs, not to have drugs in their urine. Let me give you a few examples:

-If a person takes only a small amount of a drug, it may not show up in the urine.
-When a person takes a drug, it takes a couple of hours to get into the urine, and then it will only be in the urine for a few days. So, if the urine sample is taken too early or too late, even though the person took drugs, no drugs will be found in the urine.
- It is also possible that something may have been done to the urine. If this happens you may get incorrect test results.
- The person drank a lot of liquids within a few hours of giving the sample.
-There are other drugs that a person could be taking other than the ones that we test for. If we do not find any drugs in the urine, the person tested may be using other drugs. You may want to talk to your doctor about testing for other drugs."

Emergency Calls

When the caller or donor is perceived to be a danger to themselves or others, the Telephone Representative will handle the call as an Emergency and act accordingly.

Emergency calls will usually be calls that (1) the caller makes to the Telephone Representative because they perceive their situation as an emergency (i.e., involving children) (2) are routine that convert to emergency status based upon the caller's response to results or other information provided by the Telephone Representative (i.e., positive test results) or (3) calls which convert to emergency based upon the Telephone Representative's interpretation of information provided by the caller (i.e., agitation or anger expressed by the caller, indication of suicide or self-destructive behavior).

Once the Telephone Representative perceives that a call is an emergency, they should convey this to the caller along with the reason why they interpret the call as an emergency. The Telephone Representative should then proceed to emphasize the importance of the caller accepting a referral for immediate evaluation on an emergency basis.

Representative's Response to Emergency Call:

Sir or Madame, after talking with you it seems that you have a very bad problem that you should get help for right away. You need to go to your local hospital's Emergency Room for care. I can call Emergency Services (911) in your area to help you right now.

If the caller refuses:

The Telephone Representative will encourage them to seek assistance on their own or call back to be accommodated.

Sir/Madame, you really need to get help as soon as possible. If you don't want me to call for Emergency Services (911) in your area, you really need to call as soon as we hang up. If you can't get through, or if you change your mind and want me to call, please call me right back and I'll help you. My name is _____.[Give extension if appropriate.]